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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/724,107	12/01/2003	Chiem V. Pham	000166.0106-US02	1425

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1201 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, DC 20004-2401

EXAMINER

HAMPTON HIGHTOWER, PATRICIA

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/724,107

Applicant(s)

PHAM, CHIEM V.

Examiner

Patricia Hightower

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

In view of the applicant's response filed March 15, 2005 in which it was established that the Yamamoto et al (USP 4,849,228) did not teach as claimed a ***method for preparing microparticles*** by preparing a solution using a solvent of a ***copolymer of a D,L-lactide and glycolide that comprises greater than 40 and less than 50 mole% lactide and greater than 50 and less than 60 mole% glycolide having an average glycolate monomer block length is less than about 3***, dissolving or dispersing an active agent in the solution and removing the solvent under vacuum to form microparticles; thus the rejection of the claims under 35 USC 102(b) as being anticipated by Yamamoto et al (USP 4,849,228) has been withdrawn.

However, the claims 1-17 are subject to new grounds of rejection under the judicially created doctrine of obviousness-type double patenting over USP No. 6,362,308 and USP No. 6,703,477 (both newly cited).

Obviousness-type Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 are newly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S. Patent No. **6,703,477**. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application that claims a method of preparing microparticles by preparing a solution using a solvent of a ***copolymer of a D,L-lactide and glycolide that comprises greater than 40 and less than 50 mole% lactide and greater than 50 and less than 60 mole% glycolide having an average glycolate monomer block length is less than about 3***, dissolving or dispersing an active agent in the solution and removing the solvent under vacuum to form microparticles; is viewed as claiming overlapping subject matter with the patent which claims a block and graft copolymer of D,L-lactide and glycolide comprising greater than 40 and less than 50 mole% lactide and greater than 50 and less than 60 mole% glycolide, wherein the average glycolate monomer block length is less than about 3 and another polymer or copolymer and a sustained release active agent delivery system prepared by loading an active agent into a copolymer matrix, the copolymer is dissolved in a solvent; which encompasses the claimed process of preparing microparticles.

The applicant is reminded that it is permissible to use the specification to define what appears in the claims. The patent discloses in examples 6 –16 the preparation of microparticles comprising a high glycolide content copolymer of lactide and glycolide wherein a solution is made of the polymer or copolymer and an active agent and the solution is emulsified in water or other polar solvent, the solvent is removed under vacuum and an active agent-loaded microspheres/ microparticles are collected. Due to

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the applicant employing the open language, "comprising"; it leaves the claims open to the inclusion of other reactants/components/ingredients not specifically claimed even in major amounts.

Claims 1-17 are newly rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,362,308. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application that claims a method of preparing microparticles by preparing a solution using a solvent of a ***copolymer of a D, L-lactide and glycolide that comprises greater than 40 and less than 50 mole% lactide and greater than 50 and less than 60 mole% glycolide having an average glycolate monomer block length is less than about 3***, dissolving or dispersing an active agent in the solution and removing the solvent under vacuum to form microparticles; is viewed as claiming overlapping subject matter with the patent which claims a copolymer of D, L-lactide and glycolide comprising 40-50 mole% lactide and 50-60 mole% glycolide the solubility of the copolymer is greater than about 10% in methylene chloride and the method of making the copolymer of D, L-lactide and glycolide, comprising making a mixture of the copolymer and heating said mixture so that it is substantially free of water and further collecting said copolymer in the collecting step and extruding the copolymer into liquid nitrogen and milling/particulating said copolymer. The patent clearly discloses the preparation of microparticles comprising the copolymer of D,L-lactide and glycolide by making a solution comprising the copolymer and an active agent; that clearly encompasses the instant invention. See

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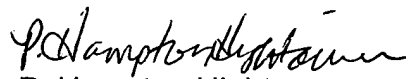
examples 6-16 in the patent. The applicant is reminded that it is permissible to use the specification to define what appears in the claims.

Applicant's arguments with respect to claims 1-17 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Hightower whose telephone number is (571) 272-1073. The examiner can normally be reached on M-F from 9:30 A.M. - 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


P. Hampton Hightower
Primary Examiner
Art Unit 1711

P. Hightower:ph
September 30, 2005